

Applicants require identification of the present application in view of the foregoing amendments and the following remarks.

#### I. Introduction

Claims 1-22 are pending. Claims 1-18 have been amended to correct improper multiple dependent claims (claims 5-13, 15 and 16), to introduce more proper transitional phrases (claims 1-18), or to correct typographical errors or improve readability or clarity. Claims 19-22 have been added to cover the subject matter deleted by the amendment of claims 1, 16, 17 and 18, respectively.

# II. Rejection under 35 USC §112, Second Paragraph

The Examiner has rejected claims 15-18 as indefinite for the use of the phrase, "such as" or "such that." Without acquiescing in the propriety of the Examiner's rejection, Applicants have obviated these rejections by amending claims 15 and 18 to delete the objected terms. Accordingly, Applicants respectfully request withdrawal of this rejection.

#### III. Rejection under 35 USC § 102

The Examiner has rejected claim 1 as anticipated by EP 648529A1 filed by Fusejima et al. ("Fusejima"). Applicants respectfully traverse this rejection.

Claim 1 is directed to a device for producing granules comprising

- (i) a drum with peripheral apertures
- (ii) a member for feeding the drum with coating or fixing substance, wherein the drum comprises <u>mutually parallel sections</u> which define the apertures between each of them.

As the Examiner clearly admits in the office action, Fusejima is silent as to the teaching of the parallel sections of the claimed invention. <u>See</u> page 3 second paragraph of the Office Action.

To anticipate a claim, each and every element of the claim must be shown in a single reference. When a claimed element cannot be found in the reference, the reference does not anticipate the claimed invention. Thus, Fusejima's failure to disclose the parallel sections is fatal to the alleged anticipation.

Further, it is incumbent upon the Examiner to identify where in the reference each element may be found. Ex parte Levy, 17 U.S.P.Q.2d 1461 (Bd. Pat. App. Intrf. 1990). Consequently, because the Examiner fails to identify a claimed element, the Examiner has failed to establish a *prima facie* case of anticipation.

Moreover, criticality or unexpected results are not relevant in determining whether the claimed invention is anticipated by the prior art. They are only relevant in the context of the obviousness of the claimed invention.

Accordingly, Applicants respectfully request withdrawal of the anticipation rejection.

### IV. Rejection under 35 USC § 103

The Examiner has rejected claims 1-18 as obvious over Fusejima. More specifically, the Examiner asserts that it would have been *prima facie* obvious for one of ordinary skill in the art to, modify Fusejima's peripheral surfaces of the frame members (51a and 51b) to obtain the claimed invention because the reference teaches the advantageous results of a gas supply passing through the inner and outer peripheral surfaces to improve the accumulation of coating material onto the granules. Applicants respectfully traverse this rejection.

A drum disclosed in Fusejima comprises a cylindrical portion (tubular body portion) and an annular duct disposed at the outside of the cylindrical portion of the drum in a manner to surround the cylindrical portion. In the drum of Fusejima, vent holes (16), formed in the cylindrical portion, with a diameter of less than the size of the granules prevent escape of the granules while at the same time allowing air to pass through the mass of particles present in the drum. See col. 5, line 53 to col. 6, line 4. On the other hand, a plurality of partition plates (52) having peripheral surfaces of the frame members (51a and 51b) in the drum of Fusejima are provided in the annular duct,

outside of the cylindrical portion, for defining a flow path of gas, resulting in easy changeover of the direction of gas in the annular duct. Thus, neither partition plates nor peripheral surfaces of the frame members are designed to participate in communication between the inside and outside of the cylindrical portion, that is, allowing gas to pass through granules.

In contrast, the claimed drum is formed with an assembly of parallel sections that define, between them, apertures. In the claimed drum, a size of apertures defined by each of two sections is adjusted to retain the granules and to allow air to pass through the mass of granules.

However, there is no hint in Fusejima that peripheral surfaces of the frame members can either form a cylindrical portion or provide a path for allowing gas to pass—through granules. Thus, parallel sections in the claimed drum are clearly differentiated from peripheral surfaces of the frame members in their structure and function.

Certainly, use of parallel sections to retain granules and to allow air to pass through the mass of granules is not apparent to one of ordinary skill in the art, based on Fusejima. Fusejima evidences no motivation in the prior art for modifying peripheral surfaces of the frame members to obtain the claimed invention. As a result, such a modification proposed by the Examiner would not have been obvious to one of ordinary skill in the art, therefore, there is no *prima facie* case of obviousness. Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

In view of the above amendments and remarks, favorable reconsideration and allowance of the application are respectfully requested. In the event that any issues remain, the Examiner is invited to telephone the undersigned with any proposal to

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Respectfully submitted,

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## **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

- Marked up rewritten claims:

  1. [Amended] Device for [the production of] producing granules[, in particular pharmaceutical granules, the device having] comprising a drum [(4)] with peripheral apertures [(25)] and a member [(30)] for feeding the drum with coating or fixing substance, [characterized in that] wherein the drum [(4)] [best] fixing substance, [characterized in that] wherein the drum [(4)] [has] comprises mutually parallel sections [(22)] which define between them the apertures [(25)].
- Device according to Claim 1, [characterized in that] wherein 2. [Amended] the sections [(22)] have edges [(23)] arranged opposite on another.
- Device according to Claim 2, [characterized in that] wherein 3. [Amended] the edges [(23)] delimit a flat face [(26) of each of the [section] sections [(22)], [the] said face facing the inside of the drum [(4)].
- 4. [Amended] Device according to any of Claims 1 to 3, [characterized in that] wherein each [section] of the sections [(22)] has a width which decreases from the inside towards the outside of the drum.
- Device according to any of Claims 1 to [4] 3, [characterized 5. [Amended] in that] wherein each [section] of the sections [(22)] has a triangular profile.
- 6. [Amended] Device according to any of Claims 1 to [5] 3, [characterized in that] wherein the sections [(22] are rectilinear and parallel to an axis [(8)] of rotation of the drum.
- 7. [Amended] Device according to any of Claims 1 to [5] 3, [characterized in that] wherein the sections [(22)] are curved.
- Device according to any of Claims 1 to [7] 3, [characterized 8. [Amended] in that] wherein the drum [(4)] has sectors [(12)] which carry the sections [(22)] and can be removed independently [of] from one another.

- 9. [Amended] Device according to any of Claims 1 to [8] 3, [characterized in that] wherein the substance feed member [(30)] is arranged in the drum [(4)].
- 10. [Amended] Device according to any of Claims 1 to [9] 3, [characterized in that] wherein the substance feed member [(30)] comprises an atomizer.
- 11. [Amended] Device according to any of Claims 1 to [10] 3, [characterized in that] wherein the substance feed member [(30)] is connected to a source of liquid [(34].
- 12. [Amended] Device according to any of Claims 1 to [11] 3, [characterized in that] wherein the substance feed member [(30)] is connected to a source of compressed air [(32).
- 13. [Amended] Device according to any of Claims 1 to [12] 3, [characterized in that it has], <u>further comprising</u> means [36 and 42] for [the] continuous supply of a gas to the interior of the drum [(4)] and for forcing the gas to pass through the apertures [(25)] from the inside towards the outside of the drum [(4)].
- 14. [Amended] Device according to [Claims] <u>Claim</u> 13, [characterized in that it has], <u>further comprising</u> means [(38)] for modifying the temperature of the gas upstream of the drum [(4)].
- 15. [Amended] Device according to Claim 13 [or 14], [characterized in that] wherein [it is set up such that] the gas passes through the apertures [(25)] from the outside towards the inside of the drum [(4).
- 16. [Amended] Process for producing granules[, in particular pharmaceutical granules], [characterized in that use is made of] wherein a device according to one of Claims 1 to [15] 3.
- 17. [Amended] Granules[, in particular pharmaceutical granules], [characterized in that they have been] produced by means of a process according to Claim 16.

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18. [Amended] Packaging [such as a sachet or gelatin capsule], [characterized in that it comprises] comprising granules according to Claim 17.